

K022890

SEP 6 2002

Summary of Safety and Effectiveness

Submitter's name, address, telephone number and contact person:

Bioplate, Inc.
6911 Melrose Avenue
Los Angeles, CA 90038
(323) 549-9500
(323) 935-0110 (fax)

Contact Person: Carol E. Jones

Trade Name of Device

Modified screw designs for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery

Common name

Bone plates and bone screws

Classification name

Bone Plate (21 CFR 872.4760)

Predicate Devices

- (1) Walter Lorenz Surgical Instruments, Inc.
Lorenz Self Drilling Screw
K013954
- (2) Synthes (USA)
Self Drilling Screw
K983485
- (3) KLS-Martin L.P.
Centre-Drive Drill Free Screw
K971297
- (4) Osteomed Corp.
Auto-Drive Bone Screw
K974785

- (5) Bioplate, Inc.
Bioplate® Rigid Fixation Bone Plating System for
Cranio-maxillofacial Surgery
K972463

Description of the device

Modified screw designs for use with the Bioplate® Rigid Fixation Bone Plating System for Cranio-maxillofacial Surgery includes titanium alloy screws of varying diameters and lengths and are used for fixation of unalloyed, commercially pure titanium and titanium alloy plates to the craniofacial bony tissue.

Intended use of the device

The modified screw designs for use with the Bioplate® Rigid Fixation Bone Plating System for Cranio-maxillofacial Surgery are intended for use in the treatment of fractures and reconstructive procedures of the cranio-maxillofacial skeleton and non-weight bearing fixation, including cranial bone fixation and orbital fixation. Each device is intended for single use only and only in conjunction with other titanium and titanium alloy implants.

Comparison of the devices' technological characteristics with those of predicate devices

The modified screw designs for use with the Bioplate® Rigid Fixation Bone Plating System for Cranio-maxillofacial Surgery has the same indications for use as the Bioplate, Inc., Walter Lorenz, Synthes USA, Osteomed Corp., and KLS-Martin predicate devices. All of the technical characteristics of the modified screw designs for use with the Bioplate Rigid Fixation Bone Plating System for Cranio-maxillofacial Surgery are substantially equivalent to the corresponding characteristics of the predicate devices, and any minor differences raise no new issues of safety and efficacy.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Ms. Carol E. Jones
Chief Operating Officer
Bioplate, Incorporated
6911 Melrose Avenue
Los Angeles, California 90038

Re: K022890
Trade/Device Name:
Regulation Number: 21 CFR 872.4760
Regulation Name:
Regulatory Class: II
Product Code: JEY
Dated: August 30, 2002
Received: August 30, 2002

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

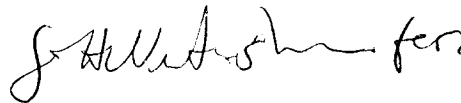
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski".

Timothy A. Ulatowski

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K022890

Device Name: Modified screw designs for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery.

Indications for Use:

The modified screw designs for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery are intended for use in the treatment of fractures and reconstructive procedures of the craniomaxillofacial skeleton and non-weight bearing fixation, including cranial bone fixation, brow fixation and orbital fixation. Each device is intended for single use only and only in conjunction with other titanium and titanium alloy implants.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Rump
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022890